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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,478	11/14/2000	James A. Laugharn Jr.	07985-012002	6793

7590

12/18/2002

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EXAMINER

LEWIS, PATRICK T

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 12/18/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,478

Applicant(s)

LAUGHARN JR. ET AL.

Examiner

Patrick T. Lewis

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72,73,75,76,78-80,82-84,91,92,98 and 99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72,73,79,80,82,91,92,98 and 99 is/are rejected.
- 7) ☒ Claim(s) 75,76,78,83 and 84 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 15.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13. 6) ☐ Other:

DETAILED ACTION

Objections/Rejections Set For the in Office Action dated July 16, 2002

1. Claims 72-80, 82-84, 91-92, and 98-99 were rejected under the judicially created doctrine of double patenting over claims 1-9 of U.S. Patent 6,120,985.
2. Claims 74 and 77 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's Response dated September 27, 2002

3. In the amendment filed September 24, 2002 claim 72 was amended and claims 1-5, 9, 11, 13-17, 59-67, 69-71, 74, 77, 93-95, 97, and 100-102 were canceled. An action on the merits of claims 72-73, 75-76, 78-80, 82-84, 91-92, and 98-99 is contained herein below.
4. In the terminal disclaimer dated September 27, 2002 applicant waived and disclaimed the terminal portion of the term of the entire patent to be granted upon the instant application to the expiration date of U.S. Patent 6,120,985, whereby the patent granted on the instant application and U.S. Patent 6,120,985 will expire on the same day.
5. In regards to rejection of claims 72-80, 82-84, 91-92, and 98-99 under the judicially created doctrine of double patenting, applicant's terminal disclaimer dated September 27, 2002 has been fully considered and has overcome the rejections set

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forth in the Office Action dated July 16, 2002 or rejections have been rendered moot in view of the cancellation of claims.

6. In regard to the rejection under 35 U.S.C § 112, second paragraph, applicant's cancellation of claims 74 and 77 has rendered the rejection moot.

Response to Arguments

7. No arguments were set forth in the Response dated September 27, 2002.

Claim Objections

8. Claims 75-76, 78, and 83-84 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 72-73, 79-80, 82, 91-92, and 98-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Frantz et al. U.S. 5,536,496 (Frantz) and Chen et al. U.S. Patent 5,104,674 (Chen).

Claims 72-73, 79-80, and 82 are drawn to a method of releasing molecules from cells, the method comprising: exposing the cells to an elevated pressure of at least 500 psi in a pressure chamber to form lysed cells whereby the molecules are released from the lysed cells within the pressure chamber. Claims 91-92 are drawn to a method of isolating a biological component from a liquid sample, the method comprising: exposing the sample to an elevated pressure in a pressure chamber, the elevated pressure being sufficient to maintain the sample in a liquid state at a subzero temperature; while maintaining the elevated pressure, reducing the temperature of the sample to the

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subzero temperature; and while maintaining the elevated pressure and the subzero temperature, isolating the biological component from the sample. Claims 98-99 are drawn a method for the isolation of molecules from cells, the method comprising: exposing the cells to a pressure of at least 500 psi in a pressure chamber to form lysed cells; and separating the molecules from the lysed cells within the pressure chamber.

Frantz teaches a method of lysing bacterial cells (column 7, lines 1-21). Frantz teaches the use of a GAULIN model 15M laboratory homogenizer as the apparatus to lyse cells and release their cellular contents. Bacterial cells in the culture fluid are lysed by continuous passage through the pressure chamber of the homogenizer. This subjects the cells to an immediate pressure drop from between an initial pressure drop of between 2000 and 5000 psi to ambient pressure of 15 psi. The lysed cells are aseptically deposited into another closed container. The lysate is then clarified by sequential steps of centrifugation and/or microporous filtration.

Frantz differs from the instantly claimed invention in that Frantz does not teach isolating molecules from the lysed cells within the pressure chamber. Frantz is silent on the temperature at which the process is performed. These deficiencies would have been obvious to one of ordinary skill in the art in view of Chen.

Chen teaches the microfragmentation of ionic polysaccharide/protein complex dispersions (column 11, lines 2-34). Chen teaches that effective results are achieved using a CD150 or MC15 cell disruptor using a knife edge homogenization element within a closely surrounding impact ring (Gaulin Corp.) at an inlet pressure of at least about 3000 psig to obtain microfragments smaller than fifteen microns. The dispersion may be

passed through a cell disruptor or other high shear zone, a sufficient number of times to provide a desired particle size. The shearing zone may be a high pressure, fluidic, acoustic or mechanically driven mill zone, such as a colloid or pin mill high shear zone (column 22, lines 22-41). Within the zone, the ionic polysaccharide/protein solution is acidified in order to initiate the formation of a complex precipitate under high shear conditions.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Frantz and Chen to arrive at the instantly claimed method. Frantz teaches a method of lysing bacterial cells via continuous passage through the pressure chamber of a homogenizer. It would have been obvious to isolate or separate the molecules from the lysed cells within the pressure chamber since Chen teaches a very similar method in wherein precipitation occurs within the pressure chamber of a homogenizer. Optimization of temperature ranges is seen to be within the purview of the skilled artisan, as differences in temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such temperature is critical. One would have been motivated to do so in order to produce free toxoid and whole bacterin-toxoid vaccine compositions.

Conclusion

13. Claims 72-73, 75-76, 78-80, 82-84, 91-92, and 98-99 are pending. Claims 72-73, 79-80, 82, 91-92, and 98-99 are rejected. Claims 75-76, 78, and 83-84 are objected to. No claims are allowed.

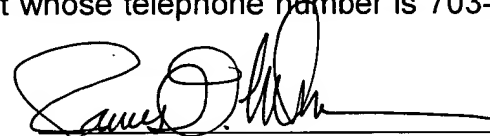
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623


James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
December 16, 2002